IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

FRESENIUS MEDICAL CARE HOLDINGS, INC., et al.,

Plaintiffs,

v.

BAXTER INTERNATIONAL, INC., et al.,

Defendants.

No. C 03-1431 SBA

ORDER

[Docket Nos. 436, 448]

This matter comes before the Court on Plaintiffs Fresenius Medical Care Holdings, Inc. and Fresenius USA, Inc.'s (collectively, "Plaintiffs" or "Fresenius") Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131 and Defendants Baxter International, Inc. and Baxter Healthcare Corporation's (collectively, "Defendants" or "Baxter") Motion for Partial Summary Judgment of Validity.

Having read and considered the arguments presented by the parties in the papers submitted to the Court, the Court finds this matter appropriate for resolution without a hearing. The Court hereby GRANTS Motion for Partial Summary Judgment of Validity [Docket No. 448] and DENIES Fresenius' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131 [Docket No. 436].

BACKGROUND

A. Procedural Background

Plaintiffs and counter-defendants Fresenius USA, Inc.[1] and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") initiated this suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity against defendants and counter-plaintiffs Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter").[2] Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 (the "'434 Patent")[3]; (2) U.S. Patent No. 5,326,476 (the "'476 Patent")[4]; (3) U.S. Patent No. 6,284,131 B1 (the "'131 Patent")[5]; (4) U.S. Patent No. 5,486,286 (the "'286 Patent")[6]; and (5) U.S. Patent No. 5,744,027 (the "'027 Patent")[7] (collectively "patents-in-suit").

Baxter is the assignee and record owner of the patents-in-suit. Baxter has commercialized the inventions of the patents-in-suit through hemodialysis instruments, such as the Drake Willcock™ System 1000 Dialysate Delivery System ("System 1000"). Amend. Ans. at ¶ 19. On May 14, 2003, Baxter answered and counterclaimed that Fresenius' 2008H and/or 2008K hemodialysis machines infringe four of the five patents.

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[1]Fresenius Medical Care Holdings, Inc. is the country's leading full service provider of dialysis care. Compl. at ¶ 4. Through various affiliates, the company treats approximately 79,600 patients in approximately 1,080 dialysis clinics throughout the United States. *Id.* Fresenius USA, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. and has a research and manufacturing facility in Walnut Creek, California. *Id.*

[2]Baxter Healthcare Corporation and Baxter International Inc. are affiliated corporations that make dialysis machines, equipment, and supplies, which are sold to dialysis clinics. Compl. at ¶ 5.

[3]The '434 Patent was issued on September 21, 1993 and claims an invention entitled "Method and Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 17.

[4]The '476 Patent was issued on July 5, 1994 and claims an invention entitled "Method and Apparatus for Kidney Dialysis Using Machine with Programmable Memory." Amend. Ans. at ¶ 26.

[5]The '131 Patent was issued on September 1, 2001 and claims an invention entitled "Method and Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 35.

[6]The '027 Patent was issued on April 28, 1998 and claims an invention entitled "Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 46.

[7]The '286 Patent was issued on April 28, 1998 and claims an invention entitled "Apparatus for Performing a Self-Test of Kidney Dialysis Membrane." Amend. Ans. at ¶ 55.

On October 9, 2003, pursuant to this Court's Patent Local Rules, Baxter served its Preliminary Infringement Contentions.

On October 20, 2003, Baxter amended its Answer and Counterclaims to assert infringement of the '286 Patent.

On November 24, 2003, pursuant to Patent Local Rule 3-3, Fresenius served its Preliminary Invalidity Contentions. After Fresenius filed a Motion to Compel Further Disclosures on December 22, 2003, Baxter served supplemental infringement contentions.

On October 14, 2004, a claim construction hearing was held on certain disputed terms. After the Court issued its claim construction ruling on November 22, 2004, the parties met and conferred in order to narrow the selection of additional terms to be construed by the Court.

On December 28, 2004, Baxter served its Final Infringement Contentions pursuant to Local Rule 3-6(a).

On January 5, 2005, Baxter filed a Motion for Partial Summary Judgment of Infringement with respect to claim 1 of the '131 Patent and claim 26 of the '434 Patent.

On January 6, 2005, the parties requested that the Court construe one additional claim term from claim 26(a) of the '434 Patent: "means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration."

On January 18, 2005, Fresenius served its Final Invalidity Contentions pursuant to Patent Local Rule 3-6(b). In its Final Invalidity Contentions, Fresenius identified the Sarns 9000, including its operation manuals, as invalidating prior art.

On February 15, 2005, Fresenius filed a Cross-Motion for Summary Judgment with respect to whether Fresenius infringed claim 1 of the '131 Patent and claim 26 of the '434 Patent. Also on February 15, 2005, Baxter filed a Motion to Strike Fresenius' Final Invalidity Contentions.

On March 1, 2005, this Court issued an order construing the remaining disputed claim term in claim 26(a) of the '434 patent.

On August 24, 2005, the Court issued an Order denying Baxter's Motion to Strike Fresenius' Final Invalidity Contentions.

On September 2, 2005, this Court issued an Order granting in part and denying in part Baxter's

Motion for Partial Summary Judgment and granting and denying in part Fresenius' Cross-Motion for Summary Judgment. The Court held that Fresenius' 2008K hemodialysis machine infringed claim 26 of the '434 Patent and claim 1 of the '131 Patent. The Court also held that the SVS, Kt/V and Blood Pressure screens of the 2008K did not infringe claim 1 of the '131 Patent.

On February 21, 2006, Fresenius filed the instant Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131, seeking partial summary judgment that: (1) the asserted claims of the '434 and '131 Patents are invalid as obvious under U.S.C. § 103(a); (2) the asserted claims of the '131 Patent are invalid as anticipated under 35 U.S.C. § 102(b) by the Sarns Manual; and (3) the touch screen claims[8] of the patents-in-suit are invalid for failure to satisfy the enablement and best mode requirements of 35 U.S.C. § 112. With respect to its obviousness defense, Fresenius requests that the Court enter summary judgment in its favor on the grounds that the '434 and '131 Patents are rendered obvious by the following prior art references: (1) the Sarns Manual; (2) U.S. Patent No. 4,756,706 issued to Kerns (referred to herein as "Kerns" or the "Kerns patent"); (3) U.S. Patent No. 4,898,578 issued to Rubalcaba (referred to herein as "Rubalcaba" or the "Rubalcaba patent"); and (4) U.S. Patent No. 4,370,983 issued to Lichtenstein (referred to herein as "Lichtenstein" or the "Lichtenstein patent").

Also on February 21, 2006, Fresenius filed a Motion for Summary Judgment seeking partial summary judgment that: (1) claim 5 of the '476 Patent and claim 11 of the '027 Patent are invalid as obvious under 35 U.S.C. § 103(a); (2) claim 7 of the '476 Patent and claims 1, 2, 4, 6-8, 10, and 12-16 of the '027 Patent are invalid as anticipated under 35 U.S.C. § 102(b); and (3) claim 5 of the '476 Patent is invalid for failure to satisfy the definiteness and enablement requirements of 35 U.S.C. § 112.

On March 7, 2006, Baxter filed a Motion for Partial Summary Judgment of Validity, seeking judgment that the asserted claims of the '434 and '131 Patents are not invalid under 35 U.S.C. § 102 for anticipation, and that the asserted claims of the '434, '131, '027, and '476 Patents do not violate the best mode and enablement requirements of 35 U.S.C. § 112.

Also on March 7, 2006, Baxter filed the following motions: (1) a Motion to Bar Fresenius'

[8]The asserted "touch screen" claims are claims 26-31 of the '434 Patent, claims 1-3 and 13-16 of the '131 Patent, claim 5 of the '476 Patent, and claim 11 of the '027 Patent.

Proffered Damages Expert Professor Rubinfeld; (2) a Motion to Strike Fresenius' Best Mode and Anticipation Defenses, in Part, Under Local Rule 3-7; and (3) a Motion to Bar the Expert Testimony of Jeff Riley.

On March 14, 2006, pursuant to a stipulation between the parties, the Court issued an Order dismissing with prejudice: (1) all claims, counterclaims, and defenses of the parties concerning the '286 Patent and claims 1 and 6 of the '476 Patent; (2) all claims, counterclaims, and defenses of the parties concerning Fresenius' 2008H hemodialysis machine; (3) Fresenius' affirmative defenses of laches, estoppel, failure to mark, and prosecution laches with respect to all of the patents-in-suit; (4) Fresenius' affirmative defense of unenforceability with respect to the '286 Patent and the '027 Patent; (5) Fresenius' defense of improper inventorship based on alleged contribution by Ziba Design with respect to all of the patents-in-suit; (6) Fresenius' defense of indefiniteness as to claims 1, 13 and 14 of the '131 Patent.

On March 21, 2006, Fresenius filed its Opposition to Baxter's Motion for Partial Summary Judgment of Validity, attaching in support several declarations, including a declaration from Richard Alan Griewski. Also on March 21, 2006, Baxter filed the following motions: (1) a Motion to Strike the Declaration of Charles Ragsdale; (2) a Motion to Strike PTO Documents as Exhibits to Fresenius' Motion for Summary Judgment of Invalidity of '434 and '131 Patents; and (3) a Motion to Strike Exhibits 1 and 13 to Fresenius' Motion for Summary Judgment of Invalidity of '476 and '026 Patents.

On March 28, 2006, Baxter also filed a Motion to Strike the Declaration of Richard Alan Griewski.

B. Factual Background

1. Hemodialysis

Dialysis is a process in which solutes transfer from one fluid compartment to another across a semipermeable[9] membrane. Ward Decl. at ¶ 10. In hemodialysis, the semipermeable membrane is contained in a device known as a dialyzer and the two fluid compartments are the blood and the dialysate, a man-made solution containing the major ionic constituents of blood. *Id.* To perform hemodialysis, a patient's blood is taken from the bloodstream and circulated through the dialyzer –

[9]A semipermeable membrane is one which allows free passage of small solutes, but which is impermeable to large solutes. *Id.*

which is sometimes referred to as an artificial kidney – where it undergoes purification. *Id.* The urea and other waste metabolites are removed through a process known as diffusion. *Id.* at ¶ 11. The purified blood is then returned to the patient's blood stream and the dialysate, containing the waste products, is discarded. *Id.* at ¶ 10.

Another principal function of hemodialysis is to remove the fluid consumed by the patient between dialysis treatments. *Id.* at ¶ 12. Fluid is removed by creating a pressure difference between the blood and dialysate sides of the dialyzer membrane so that fluid flows from the blood to the dialysate. *Id.* The rate of fluid flow depends on the pressure difference and the water permeability of the dialyzer membrane. *Id.*

In the beginning of the 1980's, hemodialysis machines consisted of simple electro-mechanical systems and changes in operating parameters during the course of treatment required an action by the operator. *Id.* at ¶ 16. However, when it was realized that some of the adverse symptoms patients experienced during dialysis could be ameliorated by varying the operating parameters during dialysis, hemodialysis machines began to incorporate microprocessor-based ultrafiltration control systems. *Id.* at ¶¶ 14, 16. Microprocessor-based control systems control the dialysate compartment pressure to achieve the desired ultrafiltration rate. *Id.* at ¶ 16. Microprocessor systems have the benefit of allowing many of the previously manual safety monitoring and alarm operations, such as pre-treatment testing of the integrity of the ultrafiltration control system and calculating predicted dialysate conductivity, to be automated, thereby making dialysis safer and more reliable. *Id.* The incorporation of a battery-based backup system also allowed important treatment parameters to be stored in the case of a power failure. *Id.*

Two strategies were also developed and incorporated into hemodialysis machines to address problems relating to fluid removal that occasionally occurred during hemodialysis. *Id.* at ¶ 17. These strategies were based on: (1) varying the rate at which fluid was removed during dialysis, which is known as ultrafiltration profiling;[10] and (2) varying the sodium concentration in the dialysate throughout

[10]The extent to which ultrafiltration affects blood pressure is determined, in part, by how rapidly excess fluid from other parts of the body enters the blood stream. *Id.* at ¶ 18. Ultrafiltration profiling allows fluid removal to be increased during times of rapid vascular refilling and decreased when

the treatment, which is known as sodium profiling.[11] *Id.* Both ultrafiltration profiling and sodium profiling were made possible by the development of ultrafiltration control systems, more sophisticated dialysate proportioning systems, and the incorporation of more advanced microprocessor technology into dialysis machines. *Id.*

To perform ultrafiltration profiling, the speed of the ultrafiltration pump is varied as a function of treatment time according to some predetermined scheme. *Id.* at ¶ 19. In general, the volume of fluid prescribed for removal varies from one treatment to the next, even for the same patient. *Id.* Thus, for ultrafiltration to be generally applicable, the computer controlling ultrafiltration must be able to adjust the absolute ultrafiltration rates associated with a given ultrafiltration profile to match the desired fluid removal target for a particular treatment. *Id.*

In sodium profiling, a higher sodium concentration is used in the dialysate at the beginning of the hemodialysis treatment so that the sodium enters the blood and maintains osmotic pressure. *Id.* at ¶ 20. Later in the dialysis process, after most urea removal has taken place, the dialysate concentration is decreased to remove the added sodium. *Id.* To perform sodium profiling, the speed of the concentrate pump is manipulated to proportion more or less concentrate to fit a predetermined time-dependent sodium concentration profile. *Id.* This process requires a mechanism to monitor and change the sodium concentration throughout the treatment, which requires the entry of additional non-conductivity data. *Id.* at ¶ 21. When sodium profiling is used, the chemical composition and non-conductivity data is used in conjunction with an algorithm programmed into the computer which calculates the expected conductivity[12] of the dialysate at a particular point in the dialysis treatment and adjusts the conductivity

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vascular refilling is slow. *Id.* at ¶ 18.

[11]Rapid rates of solute removal have the effect of driving water out of the blood into other body compartments as the body attempts to maintain osmotic equilibrium between the different water pools in the body. *Id.* at ¶ 20. This movement of water opposes vascular refilling and can decrease blood volume and blood pressure, particularly if fluid is also being removed from the blood via a dialyzer. *Id.* Sodium profiling is a means of maintaining osmotic equilibrium and maintaining patient blood volume. *Id.*

[12]Conductivity is defined as the ability of a solution to pass electrical current. 131.18:25-30. Conductivity is used as a measurement of the electrolyte composition of the dialysate. *Id.* The conductivity of dialysate varies due to the temperature and the electrolyte composition of the dialysate. *Id.*

alarm limits. *Id.*

Another feature that was eventually incorporated into hemodialysis machines was the addition of a "touch screen user interface." Touch screen user interfaces typically consist of hardware components and software components. Causey Decl. ISO Opp. to Baxter's MSJ at ¶ 16. The hardware components include a display, a touch screen that overlays the display, and associated electronics such as a touch screen controller. *Id.* at ¶ 17. The display – which is typically a CRT, LCD, or plasma display – displays images, numbers, and other information to the user. *Id.* at ¶ 18. The touch screen overlays the display and is touch-sensitive to allow the user to input information to control the device to which the touch screen user interface is connected. *Id.* at ¶ 19. The touch screen controller sends signals to the device indicating where on the touch screen overlay the user touched. *Id.* at ¶ 20. The touch screen controller is usually purchased from the supplier of the touch screen overlay. *Id.* at ¶ 20. As to the software, this is necessary to tell the device how to operate. *Id.* at ¶ 20. In the case of hemodialysis machines, the software – which runs in one or more of the microprocessors – controls the various pumps, valves, heaters, and other components of the hemodialysis machines. *Id.* at ¶ 21. The software also causes images to be created in simple or complex forms on the display portion of the touch screen user interface. *Id.* at ¶ 22. The operator of the machine responds to the images by touching the touch screen overlay, causing analog signals to be converted to digital representations as inputs to the software. *Id.* The software therefore provides the "instructions" to the hemodialysis machine for drawing images, buttons, and numbers presented on the display, reacting to the touching of the touch screen, and changing the operating behavior of the machine. *Id.*

2. Description of the '434 and '131 Patents

The patents-in-suit disclose and claim various improvements to hemodialysis machines that allow better control, operation and monitoring of hemodialysis treatment. *See* 434:Abstract, 1:5-8, 131:Abstract, 1:12-15.[13] For example, the patents-in-suit improved upon prior art dialysis machines by developing a new computer-controlled system that controls and monitors key functions such as dialysate

[13]References to the '131 and '434 Patents are cited herein as "XXX.YY" with "XXX" denoting the patent number and "YY" denoting the claim number (*e.g.*, Claim 1 of the '131 Patent is "131.1.") or "XXX.YY:ZZ" with "XXX" denoting the patent number, "YY" denoting the claim, and "ZZ" denoting the line (*e.g.*, Claim 1 of the '131 Patent at lines 1 through 10 is "131.1.1-10.").

preparation, ultrafiltration removal, and blood monitoring. 434:Abstract. The '434 and '131 Patents claim dialysis machines with user/machine interfaces. *See*, e.g., 434.26; 131.1. The '131 Patent and '434 Patent also disclose integrating a touch screen interface through which treatment parameters can be set, monitored, and changed. *See* 131.1, 434.26.

The '434 Patent is the parent application covering the particular use of a user/machine interface with a dialysis machine. *See* 434.26. The '131 Patent builds upon this technology by describing the ability to profile dialysis treatment parameters through the user/machine interface. *See* 131.1.

The only independent claims of the '434 and '131 Patents that Baxter has asserted against Fresenius are claim 26 of the '434 Patent and claim 1 of the '131 Patent, both of which are reproduced below.

Claim 26 of the '434 Patent requires:

> 26. A hemodialysis machine comprising:
>
> (a) means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer; and
>
> (b) a user/machine interface operably coupled to said dialysate-delivery means, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine for performing hemodialysis and to permit the user, by touching the indicium, to cause a change in the parameter.

434.26.

Pursuant to the Court's *Markman* Orders and the parties' agreed-upon claim constructions, the "means for controlling" limitation of claim 26 requires a microprocessor and either: (1) a heater and a temperature-sensing device; or (2) a concentrate pump. Additionally, the "means for delivering" limitation of claim 26 requires a supply pump. Part (b) of claim 26 requires "a touch screen adapted . . . to permit the user, by touching the indicium, to effect a change in the parameter."

Claim 1 of the '131 Patent requires:

> 1. A hemodialysis apparatus, comprising:
>
> (a) a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit; and

> (b) a user/machine interface operably connected to the dialysate-delivery system, the user/machine interface comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the hemodialysis apparatus, the touch screen being operable to display an indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter, and to display a time-variable profile of the operational parameter, the profile being representable as a plot of coordinates, the plot being with respect to an ordinate of values of the operational parameter and a time-based abscissa.

131.1.

As construed, part (b) of claim 1 requires that only one step of the procedure occur on the touch screen. Part (b) further requires: "(1) that the touch screen be operable to display a time-variable set of data of the operational parameter mentioned earlier in the claim, and (2) that this set of data be 'representable as a plot of coordinates, the plot being with respect to an ordinate of values of the operational parameter and a time-based abscissa.'"

The remaining asserted claims are dependent on the above independent claims and recite various additional hemodialysis machine features.

3. Prosecution History of the '434 and '131 Patents and Other PTO Proceedings

a. The '434 Patent

The '434 Patent application was filed on April 19, 1991. Before allowing the Patent, the examiner considered numerous prior art references, including U.S. Patent No. 4,366,061 and U.S. Patent No. 4,209,391, both of which disclose microprocessor-based hemodialysis machines. *See* Abernathy Decl. ISO Opp. to Fresenius MSJ I at Exs. 1, 2. The examiner also considered a number of touch screen references, including the Kerns patent, the Rubalcaba patent, and U.S. Patent Nos. 5,056,059 (the "Tivig" patent), 4,916,441 (the "Gombrich" patent), 4,873,623 (the "Lane" patent), and 4,914,624 (the "Dunthorn" patent). *See id.* at Exs. 4, 5. Both the Tivig and Gombrich patents disclose touch screens incorporated into medical devices.

In a September 1992 office action, the PTO allowed certain claims of the '434 Patent, but rejected others as obvious in view of Kerns. *Id.* at Ex. 6. In response, the applicants amended the claims and argued that Kerns did not render them obvious. *Id.* at Ex. 7. The Examiner agreed, and on September 21, 1993, the '434 Patent issued.

b. The '131 Patent

The '131 Patent application was filed on October 12, 2000. Before allowing the patent claims, the examiner considered the Lichtenstein patent, the CMS 08 Handbook, the Kerns patent, and the Rubalcaba patent. *See* Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 8.

On March 3, 2001, the examiner issued a Notice of Allowability. *Id.* at Ex. 10. The Examiner's Reasons for Allowance showed that he considered the teachings of Kerns and Rubalcaba:

> Kerns . . . and Rubalcaba each constitute medical infusion systems in which touch screen interfaces at least partly controlled input to computerized control systems; however each lacking any suggestion of the screen being operable to allow an operator to change the setting of a parameter of the type representable as a plot of coordinates with respect to an ordinate of parameter values and a time based abscissa.

Id.

On September 4, 2001, the '131 Patent issued.

c. The '240 Application

In 1992, a PTO examiner found Baxter's U.S. Patent Application No. 09/711,240 ("'240 Application") unpatentable under 35 U.S.C. § 103.6 due to the combination of the Lichtenstein patent with either the Kerns patent and/or the Rubalcaba patent. *See* Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 12. The rejected claim of the '240 Application that is relevant to the instant litigation, claim 41, reads as follows:

> 41. A hemodialysis machine, comprising:
>
> (a) means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer; and
>
> (b) a user/machine interface operably connected to said means for controlling the dialysate parameter, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine and to permit the user, by touching the indicium, to cause a change in the parameter.

See McClenahan Decl. at Ex. 32.

The Final Rejection was issued on April 11, 2002. *See id.* at Ex. 11. Thereafter, Baxter appealed the Final Rejection to the Board of Patent Appeals and Interferences (the "Board"). *Id.* The two issues on appeal before the Board were: (1) whether the examiner properly established a prima facie case of obviousness based on Lichtenstein combined with Kerns and/or Rubalcaba; and (2) whether the

available objective evidence of secondary considerations submitted at that time overcame the examiner's obviousness rejection. *Id.* In reviewing the appeal, the Board considered the following evidence of secondary considerations: (1) a declaration from Dr. John Sadler, and (2) four articles mentioning industrial design awards received by the System 1000. McClenahan Decl. ISO Fresenius MSJ I at Ex. 1. The Board did not hear live testimony from witnesses or consider third-party discovery.

In August 2003, the Board affirmed the examiner's rejection based on the specific combination of Lichtenstein with either Kerns and/or Rubalcaba. *Id.* The Board further found that the evidence of secondary considerations was insufficient to overcome the Examiner's obviousness rejection. *Id.*

Following the adverse decision by the Board, Baxter had the option to: (1) appeal to the Federal Circuit under 35 U.S.C. § 141; (2) bring a civil action against the director of the PTO in the United States District Court for the District of Columbia under 35 U.S.C. § 145; or (3) file a continuation application under 37 C.F.R. § 1.53(b). *See In re Kaghan*, 387 F.2d 398, 400-401 (C.C.P.A. 1967). Baxter chose to file a continuation of the '240 Application within the time allowed to appeal the adverse decision by the Board. *See* 37 C.F.R. § 1.304(a)(1). Claim 41 of the '240 Application became claim 53 of U.S. Patent Application No. 11/175,072 (the "'072 Application"). Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 13.

On September 20, 2005, claim 53 of the '072 Application was rejected under 35 U.S.C. § 103(a) as obvious in light of Lichtenstein, Rubalcaba, and/or Kerns. *See* March 28, 2006 McClenahan Decl. at Ex. C.

d. The '322 Application

In June 2005, the Patent Office issued a "non-final" decision rejecting claim 37 of Baxter's U.S. Patent Application No. 10/461,322 (the '322 Application), which claims priority to the '434 patent. McClenahan Decl. ISO Fresenius MSJ I at Ex. 2. Claim 37, which was the only pending claim of the '322 Application, provides as follows:

> 37. A method for the use of a dialysis apparatus comprising:
>
> Providing a dialysis apparatus for use in dialysis to a consumer, the dialysis apparatus comprising a dialysate-delivery system for supplying dialysate to a dialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a

> dialysate-monitoring unit; and
>
> a user/machine interface operably connected to the dialysate delivery system, the user/machine interface comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the dialysis apparatus, the touch screen being operable to display and indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter, and to display a time-variable profile of the operational parameter, the profile being representable as a plot of coordinates, the plot being with respect to an ordinate of values of the operational parameter and a time-based abscissa; and
>
> providing supplies that are useable with the dialysis apparatus to the consumer, the supplies including at least one of a dialyzer, a blood line, a syringe for withdrawing samples of dialysis solution from a dialysate line sample port, a syringe for a heparin pump, a hydrophobic transducer protector to place on pressure fittings, saline, a dialysate filter, dialysate concentrate, a drip chamber, a dialysate meter for testing dialysate, and a disinfectant.

See Fresenius MSJ I at 3.

The rejection of claim 37 was based in part on a prior art reference entitled the "Sarns® 3M 9000 Perfusion System Operators Manual" (hereinafter referred to as the "Sarns 9000" or the "Sarns Manual"). McClenahan Decl. ISO Fresenius MSJ I at Ex. 2.

e. The Reexamination Proceedings

On September 26, 2005, Fresenius filed a request for reexamination of the '131 Patent. *See* McClenahan Decl. ISO Fresenius MSJ I at Ex. 19. On October 18, 2005, Fresenius requested reexamination of the'434 Patent. *Id*. at Ex. 20. The Patent Office granted the requests on November 22, 2005 and January 5, 2006, respectively. *See id.* at Exs. 21, 22.

4. The Sarns 9000

The Sarns 9000 is a touch screen-controlled perfusion system, also known as a heart-lung machine. McClenahan Decl. ISO Opp. to Baxter MSJ at Ex. J (Sarns Manual at F298967). The Sarns 9000 was offered for sale and sold as of 1988. McClenahan Decl. at Ex. O (Griewski Depo. at 143:15-17); *see id.* at Ex. J (Sarns Manual at F298974).

Perfusion systems such as the Sarns 9000 are intended to substitute for the heart and lungs of a patient who is undergoing cardiopulmonary bypass ("CPB") or valve surgery when the patient's heart must be stopped temporarily. *Id.* at Ex. J (Sarns Manual at F298979); Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 222-23). Using a heart-lung machine, a perfusionist diverts the patient's

blood away from the body to an extracorporeal oxygenator, which removes carbon dioxide, oxygenates the blood, and then returns it to the patient. Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 185, 222-24).

The Sarns 9000 includes a touch screen user interface that displays data and operational parameters in both numerical and graphical formats, as illustrated by the "Main" and "Pulsatile" screens. The user can touch indicia on the touch screen to change the settings of the parameters. *Id.* at Ex. J (Sarns Manual at F298971, F299010-14, F299054-55). For example, the user can touch the "Pulse" button on the "Main" screen of the Sarns System to display the "Pulsatile" screen. *Id.* at Ex. J. (Sarns Manual at F299014).

Using the Pulsatile[14] screen, a user of the Sarns 9000 can set the pump speed to emulate the "pulsatile" pumping of the human heart. *Id.* at Ex. J (Sarns Manual at F299054-55). Specifically, the user can control, using the up and down arrows: (1) the number of pump cycles per minute (the "Rate" field); (2) the proportion of time the pump is at the higher output setting (the "Width" field); and (3) the pump speed during the lower output setting as a proportion of the pump speed during the higher output setting (the "Base" field). *Id.* In addition, the user can set the average volume of blood flow per unit time (the "Flow" field). *Id.* Once all of the components of pulsatile flow are entered, a square waveform is then displayed on the touch screen of the Sarns 9000 which graphically depicts the relationship between the maximum and minimum pumping phases of the pulsatile pump. *Id.*

The Sarns 9000 also includes five interchangeable roller pumps designed to offer the user flexibility to configure a variety of extracorporeal and drug delivery circuits as required by individual patients undergoing bypass procedures. *Id.* at Ex. J (Sarns Manual at F299036-F299045). Any one of the disclosed roller pumps is controllable via the touch screen interface and is capable of circulating fluids at controlled rates. *Id.* at Ex. J (Sarns Manual at F298871, F298978-79, F298986-87, F299061-62); *see also* Riley Decl. at ¶ 6.

The Sarns Manual states that the machine's use is for cardiopulmonary by-pass procedures

[14]Pulsatile flow is a type of blood flow that simulates the beating of the heart sometimes used during a cardiopulmonary bypass procedure when a patient's heart is stopped. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 221-22).

("CPB") only. In fact, it explicitly lists as "Indications" the following:

> The Sarns 9000 Perfusion System is indicated for use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary by-pass procedures, when used by a qualified perfusionist who is experienced in the operation of Sarns or similar equipment.

Abernathy Decl. ISO Baxter MSJ at Ex. 3 (Sarns Manual at F298979).

According to Fresenius' expert, Mr. Griewski, the Sarns Manual does not disclose that the Sarns 9000 can function as a hemodialysis machine or perform functions related to hemodialysis. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 216-18).

LEGAL STANDARD

A. Legal Standard For Summary Judgment in Patent Disputes

Under Federal Rule of Civil Procedure 56, a court may properly grant a motion for summary judgment if the pleadings and materials demonstrate that there is "no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment may be granted in favor of a defendant on an ultimate issue of fact where the defendant carries its burden of "pointing out to the district court that there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325; *see Johnston v. IVAC Corp.*, 885 F.2d 1574, 1577 (Fed. Cir. 1989).

To withstand a motion for summary judgment, the non-movant must show that there are genuine factual issues which can only be resolved by the trier of fact. *Anderson*, 477 U.S. at 250. The nonmoving party may not rely on the pleadings but must present specific facts creating a genuine issue of material fact. *T.W. Elec. Serv. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987). The court's function, however, is not to make credibility determinations. *Anderson*, 477 U.S. at 249. The inferences to be drawn from the facts must be viewed in a light most favorable to the party opposing the motion. *T.W. Elec. Serv.*, 809 F.2d at 631.

It is not the task of the district court to scour the record in search of a genuine issue of triable fact. *Keenan v. Allen*, 91 F.3d 1275, 1279 (9th Cir. 1996). The nonmoving party has the burden of

identifying with reasonable particularity the evidence that precludes summary judgment. *Id.* If the nonmoving party fails to do so, the district court may properly grant summary judgment in favor of the moving party. *See Carmen v. San Francisco Unified School District*, 237 F.3d 1026, 1028-29 (9th Cir. 2001) (even if there is evidence in the court file which creates a genuine issue of material fact, a district court may grant summary judgment if the opposing papers do not include or conveniently refer to that evidence). Although the district court has discretion to consider materials in the court file not referenced in the opposing papers, it need not do so. *Id.* at 1029. "The district court need not examine the entire file for evidence establishing a genuine issue of fact." *Id.* at 1031. However, when the parties file cross-motions for summary judgment, the district court must consider all of the evidence submitted in support of both motions to evaluate whether a genuine issue of material fact exists precluding summary judgment for either party. *The Fair Housing Council of Riverside County, Inc. v. Riverside Two*, 249 F.3d 1132, 1135 (9th Cir. 2001).

A court may grant a summary judgment motion in a patent case, as in any other case. *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1561 (Fed. Cir. 1988). In fact, the Federal Circuit has expressly recognized that summary judgment of invalidity is proper, including invalidity based on obviousness under 35 U.S.C. § 103. *See, e.g., McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1367 (Fed. Cir. 2003) (affirming grant of summary judgment of invalidity based on obviousness). But "in considering the [summary judgment] motion, the court must view the evidence in the most favorable light to the non-movant and draw all reasonable inferences in the non-moving party's favor." *Tillotson, Ltd. v. Walbo Corp.*, 831 F.2d 1033, 1037 (Fed. Cir. 1987).

Since summary judgment must be supported by "facts as would be admissible in evidence," *see* Fed. R. Civ. P. 56(e), scientific evidence produced in support of or in opposition to a motion for summary judgment must meet the standards of relevance and reliability articulated in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *See Seaboard Lumber Co. v. United States*, 308 F.3d 1283, 1301 (Fed. Cir. 2002). The Supreme Court in *Daubert* described this inquiry as follows:

> Faced with a proffer of expert scientific testimony . . . the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether

that reasoning or methodology properly can be applied to the facts in issue.

509 U.S. at 590.

B. Invalidity

Patents are presumed to be valid and the burden of establishing the invalidity of a patent rests on the party asserting invalidity. *See* 35 U.S.C. § 281. The factual findings supporting a conclusion of invalidity must be proven by clear and convincing evidence. *N.V. Akzo v. E.I. DuPont de Nemours*, 810 F.2d 1148, 1151 (Fed. Cir.1987).

1. Legal Standard for Anticipation

A patent claim is invalid as anticipated if "the invention was patented or described in a printed publication in this . . . country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharmas.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). A prior art reference may, however, anticipate "without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005); *see also Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

In determining invalidity due to anticipation, the first step involves the proper interpretation of the claims. *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1574 (Fed. Cir.1995). To ascertain the meaning of the claims, the court looks to the claim language, the specification, and the prosecution history. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1989). The other claims and expert testimony are also relevant. *Id.* "The claims should be construed as one skilled in the art would construe them." *Id.*

The second step involves determining whether the limitations of the claims as properly interpreted are met by the prior art. *Id.* "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference." *Scripps Clinic & Research Fdn. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir.1991) ("There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention"); *Hazani v. U.S. Intern. Trade Com'n*, 126 F.3d 1473, 1477 (Fed.Cir.1997).

An anticipation analysis involves a three-part inquiry. First, the trier of fact must determine whether the challenging reference is prior art. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576-78 (Fed. Cir. 1996); *Del-mar Eng'g, Lab v. United States*, 524 F.2d 1178, 1184 (Ct. Cl. 1975). Second, the fact finder must ascertain that the prior art is enabling as to put the invention in the public's possession. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F .2d 1471, 1479 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987). However, prior art patent references are presumed enabled. *In re Sasse*, 629 F.2d 675, 681 (C.C.P.A.1980). In the third step, the trier of fact must ascertain whether the doctrine of identity applies, *i.e.*, whether each element of the accused claim is present either expressly or inherently in a single prior reference. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed.Cir.1983), *cert. denied*, 465 U .S. 1026 (1984).

2. Legal Standard for Obviousness

Pursuant to 35 U.S.C. § 103, patent claims are invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). "It is black letter law that the ultimate question of obviousness is a question of law." *Richardson-Vicks*, 122 F.3d at 1479.

An obviousness analysis is based on four underlying factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations of nonobviousness, such as commercial success, copying, or long felt but unresolved need in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Secondary considerations of non-obviousness can include commercial success, long felt but unresolved need, and failure of others to solve the problem. *Id.*; *see also B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). Such considerations are not material to the issue of invalidity, however, unless there is a nexus between the evidence and the features described in the claims. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

Precedent also requires a suggestion, teaching, or motivation to combine the references relied upon, or to modify a single reference such that the claimed invention is practiced. *Brown & Williamson*, 229 F.3d at 1124-25. Evidence of a motivation to combine "may flow from the prior art references

themselves, the knowledge of one of ordinary skill in the art, or in some cases, from the nature of the problem to be solved." *Id.* at 1125 (citing *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996)).

3. Legal Standards for Enablement and Best Mode

A patent grant is issued in exchange for an enabling disclosure of an invention. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 791 (Fed. Cir. 1983). The enablement requirement of 35 U.S.C. § 112, paragraph 1, provides, in relevant part, that:

> The [patent] specification shall contain a written description of the invention, and the manner and process of making and using the [invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the [invention].

35 U.S.C. § 112. The enablement requirement is met "when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Enablement is a question of law based on underlying facts, which is tested as of the effective filing date of the application. *Id.*

Enablement is determined at the time the patent application was filed. *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345 (Fed. Cir. 2000), *cert. denied*, 532 U.S. 1019 (2001). Determining whether a disclosure of a patent satisfies the enablement requirement is a question of law. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). The legal conclusion of enablement rests on factual underpinnings. *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 690 (Fed. Cir. 2001).

A decision on the issue of enablement "requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the claimed invention without undue experimentation." *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990). Factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *In re*

Wands, 858 F.2d 731 (Fed. Cir. 1988); *Enzo Biochem v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999).

While some experimentation does not preclude enablement, the amount of experimentation must not be unduly extensive. *Atlas Powder Co.*, 750 F.2d at 1576. The test for undue experimentation allows for a considerable amount of experimentation if it is merely routine or if the patent specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

35 U.S.C § 112 also contains a best mode requirement. Specifically, section 112 requires that the inventors "shall set forth the best mode contemplated by the inventor in carrying out his invention." The purpose of the best mode requirement is "to ensure that the public, in exchange for the rights given the inventor under the patent laws, obtains from the inventor a full disclosure of the preferred embodiment of the invention." *Dana Corp. v. IPC Ltd. P'ship*, 860 F.2d 415, 418 (Fed. Cir. 1988). A party challenging the validity of a patent based on best mode must establish, by clear and convincing evidence, that the inventors concealed the best mode known to them of practicing the claimed inventions. *High Concrete Structures, Inc. v. New Enterprise Stone & Lime Co., Inc.*, 377 F.3d 1379, 1382 (Fed. Cir. 2004).

Invalidation for failure to describe the best mode requires the Court to determine whether: (1) the inventor knew of a better mode than was disclosed; and (2) the inventor intentionally concealed that better mode. *Id.* at 1382-83; *Bayer AG v. Schein Pharmaceuticals Inc.*, 301 F.3d 1306, 1320 (Fed. Cir. 2002). "It is concealment of the best mode of practicing the claimed invention that [35 U.S.C. § 112(1)] is designed to prohibit." *Randomex Inc. v. Scopus Corp.*, 849 F.2d 585, 588 (Fed. Cir. 1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85 (Fed. Cir. 1986) ("In order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed."). The best mode requirement is not violated by the unintentional omission of information that would be readily known to persons in the field of the invention. *High Concrete Structures, Inc.*, 377 F.3d at 1383.

ANALYSIS

A. Anticipation

In its Motion for Partial Summary Judgment, Baxter requests that the Court enter judgment in its favor on Fresenius' anticipation affirmative defense. Specifically, Baxter asks the Court to find that claims 26-31 of the '434 Patent and claims 1-3 and 13-16 of the '131 Patent are not anticipated by the Sarns 9000. In its own Motion for Summary Judgment, Fresenius asks the Court to find that the '131 Patent is anticipated by the Sarns 9000 as a matter of law. Although considered a question of fact, anticipation is appropriate for summary judgment if no genuine issue of material fact exists. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001) (affirming summary judgment of invalidity where "no reasonable jury could find" the patent valid in light of the prior art).

As a preliminary matter, the Court notes that Fresenius has not separately moved for a summary judgment finding of anticipation with respect to the '434 Patent and specifically states in its Opposition to Baxter's Motion that it is *not* arguing that the '434 Patent is anticipated by the Sarns 9000 because "the asserted claims [of the '434 Patent] include one or more means-plus-function limitations which, properly construed, are not fairly met by the Sarns System alone." Accordingly, the Court hereby GRANTS summary judgment in Baxter's favor and find that the '434 Patent is not anticipated by the Sarns 9000.

With respect to the asserted claims of the '131 Patent, Fresenius bears the burden of proving by clear and convincing evidence "strict identity" between the claimed invention and the Sarns 9000 such that ***each and every*** claim limitation is described in the reference. *Trintec Indus., Inc. v. TOP-U.S.A. Corp.*, 295 F.3d 1292, 1295-96 (Fed. Cir. 2002); *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 994-95 (Fed. Cir. 2000). If there is even one claim element missing in the Sarns 9000, Fresenius' invalidity defense fails and Baxter is entitled to summary judgment.

To meet its burden, Fresenius asserts that part (a) of claim 1 of the '131 Patent,[15] which recites a "dialysate-delivery system for supplying dialysate to a hemodialyzer," is only an intended use or function of the patent and not a structural limitation. Fresenius further contends that the asserted claim limitation merely requires a system, such as a pump, capable of supplying dialysate to a hemodialyzer when a hemodialyzer is connected to the system and that the Sarns 9000 fully meets this claim

[15]The parties focus on claim 1 of the '131 Patent because it is the only independent claim and because dependent claims are not anticipated, as a matter of law, if the claim upon which they depend is not. *See Hartness Int'l v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108 (Fed. Cir. 1987).

limitation.[16]

In response, Baxter argues that Fresenius' anticipation defense fails for the following reasons: (1) claim 1 of the '131 Patent requires "a hemodialysis apparatus" which, pursuant to the parties' agreed upon construction, is a "kidney dialysis machine that removes metabolic waste from the patient's blood by circulating the blood through an extracorporeal circuit"; (2) claim 1 requires a number of hemodialysis-specific features; (3) the Sarns Manual does not disclose that the Sarns 9000, a heart-lung machine, can function as a"hemodialysis apparatus," and the Manual does not disclose that the Sarns 9000 can perform any of the hemodialysis-specific functions required by the claims; (4) the Sarns 9000 does not have a "time-variable profile" and a "time-based abscissa" required by claim 1 of the '131 Patent; and (5) the secondary articles cited by Fresenius are outside of the "four corners" of the Sarns Manual and therefore fail to render the Sarns 9000 a hemodialysis machine.

The Court finds Baxter's arguments persuasive and, as set forth in greater detail below, Baxter has convincingly established that it is entitled to summary judgment on this anticipation defense.

1. Interpretation of the Claims

The first step in determining validity due to anticipation involves the proper interpretation of the claims. *Elmer*, 67 F.3d at 1574. Accordingly, this Court must first address whether claim 1 of the '131 Patent requires a "hemodialysis apparatus." To ascertain the meaning of a patent claim, a court may look to the claim language, the specification, and the prosecution history. *SmithKline Diagnostics, Inc.*, 859 F.2d at 882.

Baxter argues that the entirety of the '131 Patent, including its Title, Abstract, Background, and Detailed Description,[17] make clear that the inventions relate *only* to hemodialysis machines or

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[16]Specifically, in Fresenius' third supplemental response to Interrogatory No. 6 Regarding Invalidity, Fresenius states that: "Performance of hemodialysis during bypass simply require[s] the addition of a dialyzer to the extracorporeal circuit of the perfusion system and the use of one of the roller pumps of the perfusion system to circulate dialysate to the dialyzer. The system disclosed by the Sarns System is inherently capable of accepting a dialyzer in its extracorporeal circuit and using one of its five touch screen controlled roller pumps to circulate dialysate to the dialyzer." *See* Abernathy Decl. ISO Baxter MSJ at Ex. 7.

[17]The Title of the '131 Patent is "Method and Apparatus for Kidney Dialysis." The Abstract states that "[a] number of improvements relating to methods and apparatuses for kidney dialysis are disclosed." The Field of the Invention provides that "[t]he present invention relates to improvements

apparatuses and that to find otherwise would be improperly reading the claims as calling for a "medical apparatus." Fresenius, on the other hand, contends that the preamble to the '131 Patent, which requires a hemodialysis apparatus, is not a limitation as a matter of law because a claimed apparatus must be considered only in light of what it is and not what it does. In support of its argument, Fresenius relies heavily on *In re Schrieber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (holding that a claimed popcorn-dispensing device was anticipated by a prior art oil-dispensing can even though the prior art never contemplated the intended use or function that was recited in the body of the claim) and *In re Hack*, 245 F.2d 246, 248 (C.C.P.A. 1957) (recognizing the "principle that the grant of a patent on a . . . machine cannot be predicated on a new use of that machine").

Fresenius' reliance on *Schrieber* and *Hack* is misplaced, however. Contrary to Fresenius' assertion, the Federal Circuit did not hold, in *Schrieber*, that language pertaining to a patent's function may never be given patentable weight. Instead, the Federal Circuit found that, based on the facts of that particular case, the functional limitations of the asserted claims were inherent in the prior art reference. *Schrieber*, 128 F.3d at 1478. Further, *Hack* merely stands for the general proposition that one cannot patent an old product based on a newly discovered use. *Hack*, 245 F.2d at 248.

Notwithstanding the holdings of *Schrieber* and *Hack*, the Federal Circuit has repeatedly instructed that the preamble *must* be construed as a limitation of the claim when it provides antecedent basis for terms in the body or recites essential structure for the invention. "When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention." *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1306 (Fed. Cir. 2005) (citing *Eaton Corp. v. Rockwell Int. Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003)). Here, the term "hemodialysis apparatus" appears in the body of the claim and the only possible antecedent basis for that term is from the preamble. Thus, Fresenius has not shown that the patentee is using the preamble "only to state a purpose or intended use for the invention" and has otherwise defined "a structurally complete invention in the claim body." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997); *Kropa v. Robie*, 187 F.2d 150, 152 (C.C.P.A. 1951).

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in kidney dialysis machines." *See* 131:1:13-14.

Additionally, the Federal Circuit has held that language of essential structure and purpose in a preamble provides "positive limitations to the invention claimed." *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 1256-57 (Fed. Cir. 1998) ("To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality. The invention is restricted to those fibers that work as waveguides as defined in the specification."); *Trintec Indus.*, 295 F.3d at 1296 ("[t]he difference between a printer and a photocopier may be minimal and obvious to those of skill in the art. Nevertheless, obviousness is not inherent anticipation."); *Poly America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1309-10 (Fed. Cir. 2004).

Here, the terms "hemodialysis" and "dialysate" not only appear in the preamble, but also in the body of the claim. In fact, the words "dialyzer," "hemodialyzer" and "dialysate" are all present in the claim. Moreover, the word "dialysate" is found independently or tied to other structural elements *seven* times in claim 1 of the '131 Patent. Additionally, claim 1 specifically requires the structural element of "a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the *hemodialysis apparatus*." *See* 131:1-3, 13-16 (emphasis added). Because the Federal Circuit has expressly held that the functional language in the body of a claim cannot be ignored, the presence of these specific terms in the body of the claim is a strong reason why patentable weight must be given to the terms. *See Gerber Garment Technology, Inc. v. Lectra Systems, Inc.*, 916 F.2d 683, 689 (Fed. Cir. 1990); s*ee also Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 810-811 (Fed. Cir. 2002) ("[b]y virtue of its [the intended use] inclusion in the body of Claim 25, this phrase limits Claim 25"). In fact, if this Court were to adopt Fresenius' position, the Court would be reading the words "hemodialyzer" and "dialysate" out of the claim. This the Court cannot do. It is well established that "all claim terms are presumed to have meaning." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004).[18]

Since the asserted claims of the '131 Patent require a hemodialysis apparatus, and since it is beyond dispute that the Sarns 9000 is a heart-lung machine and *not* a "hemodialysis apparatus," Baxter

[18]While Fresenius also relies heavily upon *IMS Tech., Inc. v. Hass Automation, Inc.*, 206 F.3d 1422, 1434 (Fed. Cir. 2000), this case does not support Fresenius' theory. The term at issue in *IMS* ("control apparatus") was not found in the body of the claim – it *only* appeared in the preamble. *IMS*, 206 F.3d at 1427-28.

is entitled to summary judgment on this basis alone. However, the Court is also persuaded by the additional reasons Baxter has set forth as to why the '131 Patent is not anticipated by the Sarns 9000.

2. "Dialysate-Delivery System" Limitation

For example, Baxter has persuasively shown that the Sarns 9000 does not meet the claim limitation requiring a "dialysate-delivery system."[19] According to Fresenius' own expert, Mr. Causey, a "dialysate-delivery system" includes, at a minimum, a pump, a dialysate reservoir, a membrane system, and a control system, such as a microcontroller or microprocessor. Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 48:10-49:24). In light of this testimony, Fresenius' argument that element (a) of claim 1 merely requires "a pump that can circulate dialysate" is unavailing. Further, even assuming, *arguendo,* that claim 1 of the '131 Patent merely requires a pump, then at most there is a dispute of fact as to whether the roller pumps on the Sarns 9000 are accurate enough to perform any hemodialysis functions. *See* Bruner Decl. at ¶¶ 19-27 (opining that the pumps on the Sarns 9000 are not capable of performing hemodialysis functions); *see* Riley Decl. at ¶ 6 (stating that "[a]ny of the five roller pumps on the Sarns 9000 is capable of delivering dialysate to a hemodialyzer"). As such, Fresenius still would not be entitled to summary judgment in its favor on this defense.

3. The "Time-Variable Profile" Limitation

Additionally, Baxter has shown that the Pulsatile screen described in the Sarns Manual does not meet the "time-variable profile" claim limitation. Fresenius argues that the graph depicted on the Pulsatile screen is a "time-variable profile" with a "time-based abscissa" because it is a graphical depiction of the relationship between pump speed and time. McClenahan Decl. ISO Opp. to Baxter MSJ at Ex. J (Sarns Manual at F299054) ("[T]he x axis represents time while the y axis represents speed."). In support of this argument, Fresenius relies on the fact that, in the June 2005 office action, the Patent Office concluded that the Sarns System meets the "time-variable profile" and "time-based abscissa" limitations. However, as this Court has previously noted, and as set forth in greater detail with respect to the obviousness analysis, a patent examiner's findings alone are insufficient to merit summary

[19]Part (a) of claim 1 recites "a dialysate-delivery system for supplying dialysate to a hemodialyzer." The dialysate-delivery system may comprise either "a dialysate-preparation unit," "a dialysate-circulation unit," or "a dialysate-monitoring unit."

judgment on the issue of validity. *S3, Inc.*, 1999 U.S. Dist. LEXIS 23218 at *86-87 (N.D. Cal. 1999) (Armstrong, J.). Rather, a district court must review a patent's validity independently of the patent examiner. *Id.*; *see also Quad Env. Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 876 (Fed. Cir. 1991). Accordingly, this Court must make its own determination as to whether Fresenius has met its burden, in these proceedings, of producing clear and convincing evidence that the Sarns 9000 meets the "time-variable profile" limitation.

Fresenius has not met this burden, largely because the current position it has taken with respect to the Pulsatile screen flatly contradicts the position it took with respect to infringement. Specifically, when arguing that certain screens of Fresenius' 2008K machine did not infringe the '131 Patent, Fresenius stated:

> Baxter accuses three alleged parameters associated with Kt/V of being 'the operational parameter' called for in element (b) of Claim 1 of the '131 patent . . . . ***None of these alleged parameters, however, is varied over the course of the treatment***. Rather, each one is entered, if at all, as a single number, which remains constant during the treatment. ***Because these three alleged parameters do not vary over time, no 'time variable profile' of them is ever displayed***.

See Fresenius Opp. to Baxter Mot. for Partial SJ of Literal Infringement at 18:8-16 (emphasis added).

This argument was based on the opinion testimony of Fresenius' expert, Mr. Crnkovich, who stated:

> None of these alleged parameters, however, is varied ***over the course of the treatment***. Rather, each one is entered, if at all, as a single number, which remains constant during the treatment. Because these three alleged parameters do not vary over time, no "time-variable profile" of them is ever displayed.

Abernathy Decl. at Ex. 19 (Crnkovich Decl. at ¶ 32) (emphasis added).

Fresenius cannot contend that the "time-variable profile" limitation must be construed one way to avoid infringement and then argue for another construction of the claim limitation to invalidate the patent.[20] It has long been held that "[a] patent may not, like a 'nose of wax,' be twisted one way to avoid anticipation and another to find infringement ." *Sterner Lighting, Inc. v. Allied Elec. Supply, Inc.*, 431

[20]Notably, the Court adopted Fresenius' position when it granted summary judgment in Fresenius' favor on the issue of whether the Kt/V screens literally infringed the '131 Patent.

F.2d 539, 544 (5th Cir.1970).[21]

Further, as Baxter points out, although the Sarns Manual does state that the "x-axis represents time," the Manual also makes clear that what is actually displayed on the x-axis is not "time" in the sense of the "course of treatment," but rather "a proportion (%) of one pump cycle." Abernathy Decl. ISO Baxter MSJ at Ex. 3 (Sarns Manual at F299055). Additionally, it is undisputed that each component of pulsatile flow (Rate, Width and Base) is entered as a single number and remains constant during the entire procedure. *Id.* In fact, several of Fresenius' witnesses testified to the fact that the relationship between the maximum and minimum pumping phases remains constant and can only be changed manually by the operator.

For example, when explaining the static nature of the pulsatile waveform, Mr. Griewski stated:

> Q. [Y]ou, I think, testified earlier that referring to the pulsatile waveform, it would not show more than two cycles of the pulsatile waveform because it would show more repetition of the same thing. Do you recall that?
>
> A. Yes.
>
> Q. What did you mean by that?
>
> A. Well, to hopefully -- hopefully clarify it, what it means is that when the user inputs these values, then until the user changes them again, that it would be essentially duplicate information. So another way maybe to say that - say this is if I went to the screen and I put, you know, zero at this side for the number of cycles, then you would see one of those kind of like dot, dot, dot, you know, and then another. So it -- it would be sort of silly on the screen to -- you know, to represent any more than -- than the two -- than the two cycles. The two-cycle graphical image is to allow the user to better see the relationship between the peaks and the valleys.
>
> Q. If I understand your testimony correctly, the waveform is fixed?
>
> A. It's fixed until the user alters it.
>
> Q. Right. And it's fixed and cannot vary unless the user changes it during treatment.
>
> A. Yes, sir.

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[21]Further, while Fresenius now argues that the Court should not construe the patent in this manner, this construction is, in fact, consistent with the '131 Patent specification. (131:9:19:23 ("[t]he x-axis represents treatment period"); 131:9:48-54 ("Before permitting the user to program the sodium profile . . . [i]f the treatment time was not earlier programmed, the machine also solicits this data"); 131:18:11-20 ("treatment time and target UF volume have been entered and a machine-calculated UF rate is used")).

Abernathy Decl. at Ex. 4 (Griewski Depo. at 240-41).

Additionally, Fresenius' expert, Mr. Causey, testified:

> Q. Is it your understanding that the relationship between the maximum and minimum pumping phases remains constant throughout treatment, unless the operator changes it?
>
> A. I believe that to be the case, but I would have to go back and review the manual, but I can't recall it automatically changing.
>
> . . .
>
> Q. Once that phenomenon occurs, the pulsatile flow does not change across treatment time?
>
> A. I believe it's repeated and - and stable at that - at that blood volume per time until changed by the operator, and I believe that morphology is constant until its changed by the operator.

Abernathy Decl. at Ex. 10 (Causey Depo. at 165-66, 173).

Since it is undisputed that the square waveform represents two beats of a human heart, Baxter has shown that the profile is not a "time-based profile" because the profile displayed on the Pulsatile screen is fixed and spans only a few seconds[22] rather than over the course of the treatment.

Thus, based on Fresenius' own admissions, the Sarns 9000 does not meet the "time-variable profile" claim limitation.

4. Inherent Anticipation

Finally, Baxter has shown that Fresenius' "inherent anticipation" argument is without merit. Fresenius argues that, even if the phrase "for supplying dialysate to a hemodialyzer" in claim 1 is given patentable significance, the asserted claims of the '131 patent are inherently anticipated. A prior art reference may anticipate "without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005); *Cont'l Can Co.*, 948 F.2d at 1268.

Fresenius' inherent anticipation argument is premised on its contention that it was common knowledge to those of ordinary skill in the art – at least as early as 1979 – that during cardiac surgery,

[22]Sixty beats per minute translates into one beat per second, meaning the waveform displayed would span less than two seconds, a fact Fresenius' expert Mr. Causey conceded. Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 163).

toxins and fluids could be removed by adding a dialyzer and dialysate to the extracorporeal circuit of a perfusion system used during cardiac bypass surgery in the same way these items would have been added to the extracorporeal circuit of a hemodialysis machine. To support its inherent anticipation argument, Fresenius relies on four articles (referred to herein as "the Perfusion Articles"), which purportedly describe performing hemodialysis during open-heart surgery: (1) Soffer et al., *Interoperative Hemodialysis During Cardiopulmonary Bypass In Chronic Renal Failure*, J. Thoracic and Cardiovascular Surgery, Vol. 77 (1979); (2) Hakim et al., *Haemodialysis and Hemofiltration on Cardiopulmonary Bypass*, Thorax, Vol. 40 (Feb. 1985); (3) Wiggins et al., *Simultaneous Cardiopulmonary Bypass and Dialysis*, Journal of Extra-Corporeal Technology, Vol. 17, No. 3 (Fall 1985); and (4) Murkin et al., *Hemodialysis During Cardiobypass*, Anesthesia and Analgesia, Vol. 66, No. 9 (Sept. 1987).[23] *See* Abernathy Decl. at Exs. 13-16. According to Fresenius' main expert witness, the Perfusion Articles establish that "the Sarns System could be used to perform kidney dialysis during cardiac bypass procedures by adding a dialyzer to the extracorporeal circuit of the perfusion system." *See* Abernathy Decl. ISO Baxter MSJ at Ex. 18 (Causey Report at 107).

Fresenius' argument necessarily fails, however, because none of the Perfusion Articles even mentions the Sarns 9000. *Continental Can Co.*, 948 F.2d at 1268 (holding that when resorting to "extrinsic evidence" to fill a gap in a reference, "such evidence must make clear that the missing descriptive matter is necessarily present"). While it is sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference, "[s]uch factual elaboration is necessarily of limited scope and probative value, for a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Because there is no mention of the Sarns 9000 in the articles, Baxter is correct that the Perfusion articles are outside of the "four

[23]Fresenius also relies on a fifth perfusion reference entitled: *Hemofiltration, Dialysis, and Blood Salvage Techniques During Cardiopulmonary Bypass*, printed in Cardiopulmonary Bypass Procedures: Principles and Practice (1993). *See* Abernathy Decl. ISO Baxter MSJ at Ex. 17. However, since this article was published *after* the priority date for the '131 Patent, it has not been considered by the Court.

corners" of the Sarns Manual and are not clear and convincing evidence of anticipation. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000).

In fact, Fresenius' own witness has admitted that he is not aware of any publications showing that the Sarns 9000 has ever been used to perform hemodialysis:

> Q. Are you aware of any published literature describing the use of the Sarns 9000 to perform hemodialysis?
>
> A. No, I'm not.

Abernathy Del. at Ex. 9 (Riley Depo. at 200:13-21); *see also id.* at Ex. 10 (Causey Depo. at 241:8-16).

Moreover, although the Perfusion Articles generally discuss hemodialysis performed on patients during open-heart procedures, they do ***not*** specifically disclose using a heart-lung machine for that purpose. *See* Abernathy Decl. ISO Baxter MSJ at Exs. 13-16. In fact, each of the articles makes clear that a separate pump, hemodialysis machine and/or vacuum source is always required. *Id.*

Thus, Fresenius has not established by clear and convincing evidence that the Perfusion articles even suggest that heart-lung machines could be used during open-heart surgery to perform hemodialysis, and there is no evidence that the Sarns 9000 was used this manner. This precludes a finding of "inherent" anticipation. Even if the Sarns 9000 could have been used for hemodialysis, the law is clear that inherent anticipation "may not be established by probabilities or possibilities." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

Accordingly, based on all of the aforementioned reasons, the Court hereby GRANTS Baxter's Motion for Summary Judgment with respect to the anticipation affirmative defense and DENIES Fresenius' Motion for Summary Judgment on anticipation.

B. Obviousness

In its Motion for Summary Judgment, Fresenius also alleges that it has established a strong case of obviousness due to its contention that the Sarns Manual, when combined with Kerns, Rubalcaba, and Lichtenstein, renders the asserted claims of the '131 and '434 Patents obvious.[24] Baxter, on the other

[24]Because the '434 and '131 Patents have a priority date of April 19, 1991, their validity with respect to other patents, printed publications, and public use within the United States is judged as of one year before the priority date, or April 19, 1990. *See* 35 U.S.C. § 102(b). Kerns and Rubalcaba issued on July 12, 1988 and February 6, 1990, respectively. Lichtenstein issued February 1, 1983. There is

hand, has not moved for summary judgment on this issue and argues that there are numerous disputed material facts precluding summary judgment, including: (1) whether the Sarns Manual and the cardiopulmonary bypass related materials are "analogous art"; (2) whether one skilled in the art[25] would have any "motivation to combine" Lichtenstein with Kerns, Rubalcaba or the Sarns Manual; (3) whether Lichtenstein teaches away from a user entering operational parameters, or teaches any control at all by the user; and (4) whether the secondary considerations overcome any showing of obviousness.[26]

The Court finds that Baxter is correct that the disputed facts necessitate the denial of Fresenius' summary judgment motion. The relevant arguments are summarized below.

1. Whether the Sarns Manual is Analogous Art

An obviousness analysis is based on four underlying factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations of nonobviousness, such as commercial success, copying, or long felt but unresolved need in the art. *Graham*, 383 U.S. at 17-18. As such, the first step in the obviousness analysis is determining whether a patent or publication is in the prior art under 35 U.S.C. § 103.[27] "Although § 103 does not, by its terms, define the 'art to which [the] subject matter [sought to be patented] pertains,' this determination is frequently couched in terms of whether the art is analogous or not, *i.e.*, whether the art is 'too remote to be treated as prior art.'" *In re Clay*, 966 F.2d 656, 658-659 (Fed. Cir. 1992). Whether something legally within the prior art is "analogous" is a

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no dispute that Kerns, Rubalcaba, and Lichtenstein have priority to the '434 and '131 Patents. There is also no dispute that the Sarns 9000 was offered for sale and sold no later than 1988.

[25]The parties agree that the level of ordinary skill in the art is an engineer, such as a bioengineer electrical engineer, with a Bachelor of Science degree or equivalent experience, having at least three years of experience designing medical instruments and access to skilled medical personnel familiar with hemodialysis.

[26]The Court notes that, with respect to the secondary considerations factor, Baxter argues that the fact that Fresenius has patented touch screen technology supports a finding that the '131 Patent and the '434 Patent are nonobvious. However, as Fresenius points out, this is not a relevant *Graham* factor and merely confuses the issue by referring to patents that are not before the Court. As such, this argument has not been considered.

[27]Patent claims are invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

question of fact. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 n. 9 (Fed. Cir. 1987). "Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Here, the parties dispute whether the Sarns Manual, and other cardiopulmonary bypass-related materials, are "analogous art." In support of its assertion that the prior art references are "analogous," Fresenius argues that cardiopulmonary bypass materials are analogous because the applicable field of endeavor is "multi-parameter medical machines." To prove this contention, Fresenius relies on the expert report of Mr. Causey and the findings of the PTO office.[28] *See* March 28, 2006 McClenahan Decl. at Ex. J. In fact, Fresenius specifically asserts "the Court need only look to what the Patent Office has already done to see that Lichtenstein and the Sarns System are both analogous prior art." Fresenius MSJ I at 16:7-14 (stating also that "[i]f the Examiner [in the June 2005 Office Action] did not believe that the Sarns Manual is analogous prior art, he would not have relied on it."). Baxter, however, argues that Fresenius has too broadly defined the field of endeavor and that the pertinent field relates only to hemodialysis, not all medical machines. To support its position, Baxter points to the specifications of the '434 and '131 Patents, which explicitly define the "field of endeavor" as "hemodialysis." Baxter also notes that the Title and Abstract of both Patents refer exclusively to hemodialysis machines. 434:1:5-6, 131:1:13-14. Additionally, Baxter notes that every claim in the '434 and '131 Patents requires either a hemodialysis machine or a hemodialysis apparatus. Due to these conflicting factual issues, the Court cannot conclude that Fresenius has carried its burden of establishing that cardiopulmonary bypass references are analogous art as a matter of law.

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[28]Fresenius also asserts that the structure of the Sarns 9000 is so similar to the claimed hemodialysis machine that the Court may conclude that cardiopulmonary bypass machines are "unquestionably analogous art for the purposes of the obviousness analysis." Fresenius' support for this proposition, however, is the expert report of Mr. Riley, who is only being admitted as a "teaching" expert to provide general background information on the Sarns 9000 and hemodialysis. As Fresenius concedes in its opposition to Baxter's Motion to Bar the Expert Testimony of Riley, Mr. Riley has not read the patents-in-suit and therefore is not being offered as an expert on the validity of the patents-in-suit. As such, the Court has not considered this argument as clear and convincing proof that the Sarns 9000 is analogous prior art.

Further, Baxter has also produced evidence that arguably casts doubt on Fresenius' expert's contention that the problem the inventors were trying to solve was "to select and design an appropriate user interface for a medical machine." *See* March 28, 2006 McClenahan Decl. at Ex. J (Causey Expert Report at ¶ 117). For example, Baxter has elicited admissions from the design team of the Fresenius 2008K that they have no recollection of ever having read or reviewed any cardiopulmonary bypass references prior to having designed the machine. Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 25. Additionally, neither the Fresenius engineers nor the inventors of the patents-in-suit had even heard of the Sarns 9000 until after this litigation began. Further, Baxter has produced testimony from its expert, Dr. Bruner, who has stated that the problems facing designers of hemodialysis machines differed significantly from those faced by engineers in the field of cardiopulmonary bypass procedures. Bruner Decl. at ¶¶ 11-18, 28. As a result of these disputed facts, the Court concludes that the first criterion of the obviousness test has not been met as a matter of law because a reasonable juror could find that the prior art references and the claimed subject matter are either not in the same field of endeavor or not pertinent to the particular problem the inventors were trying to solve. *See, e.g., Wang Labs, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864-865 (Fed. Cir. 1993).

2. Motivation and the Teachings of Lichtenstein

Another issue that is in dispute is whether one skilled in the art would have any "motivation to combine" Lichtenstein with the other prior art references. "In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have lead a person of ordinary skill in the art to select the references and combine them in a way that would produce the claimed invention." *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001). Motivation to combine may be found in the prior art references themselves, the knowledge of those skilled in the art, or in the nature of the problem itself. *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 1996). The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

Fresenius contends that it is entitled to summary judgment because the Patent Board "has already determined that one of ordinary skill in the art would have been motivated to combine a touch screen

user interface such as that disclosed in Kerns, Rubalcaba, or the Sarns Manual with a computer-controlled hemodialysis machine such as that disclosed in Lichtenstein." Indeed, in the August 2003 Opinion, the Board noted that:

> From a number perspectives, the use of a touch screen input/output device for computer control purposes in both types of modular apparatuses used for medical purposes in similar manner would have been readily suggested to one of ordinary skill in the art by the very nature of the apparatuses and the known attributes of a touch screen input/output device user interface with respect to such apparatuses[.]

McClenahan Decl. ISO Fresenius MSJ at Ex. 1.

In the June 2005 Office Action, the examiner also noted that there would have been a motivation to combine a touch screen user interface with a hemodialysis machine. In fact, he stated:

> It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the dialysis procedure as disclosed in the CMOS Manual to include utilizing a touch screen for entry of rates, volumes and profiles, as taught by the Sarns Manual . . . .

McClenahan Decl. at Ex. 2.

The PTO's findings certainly support Fresenius' case. However, as this Court previously noted, a patent examiner's findings alone are insufficient to merit summary judgment in favor of the accused infringer on the issue of obviousness. *S3, Inc.*, 1999 U.S. Dist. LEXIS 23218 at *86-87. This is especially true in light of the fact that a PTO examiner is only required to provide evidence which "as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a prima facie case of obviousness) is more probable than not." MPEP § 2142 (emphasis added). Thus, before granting summary judgment, a district court is required to review a patent's validity *independently* of the patent examiner. *Id.*; *see also Quad Env. Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 876 (Fed. Cir. 1991). An independent analysis is critical even when reexamination proceedings are ongoing with respect to the patents-in-suit. As stated by the Federal Circuit in *Quad*,

> In an infringement suit before a district court, the invalidity of a patent under 35 U.S.C. § 103 must be decided on the basis of prior art adduced in the proceeding before the court. The issue cannot be decided merely by accepting or rejecting the adequacy of the positions taken by the patentee in order to obtain a Certificate of Reexamination for the patent. . . . The courts are the final arbiter of patent validity and, although courts may take cognizance of, and benefit from, the proceedings before the patent examiner, the question is

> ultimately for the courts to decide, without deference to the rulings of the patent examiner.

Id. at 876 (internal citations omitted); *see also Greenwood v. Hattori Seiko Co., Ltd.*, 900 F.2d 238 (Fed. Cir. 1990) (reversing summary judgment because district court relied solely on examiner's decision to find patent invalid).

Accordingly, before Fresenius can prevail on its defense, Fresenius must offer its own citations to, and analysis of, specific prior art. *Id.* Because Fresenius relies solely on the aforementioned PTO proceedings, and has not cited to any testimony from its expert witnesses, evidence obtained through the three-and-a-half years of discovery in this case, or admissions from Baxter witnesses, the Court concludes that Fresenius has not sufficiently established, through clear and convincing evidence, that it is entitled to judgment as a matter of law.

Further, with respect to the issue of "motivation," Baxter has shown that there are disputed material issues that must be resolved before a finding of obviousness can be made. For example, Baxter argues that, despite the PTO's findings, a person of ordinary skill would never be motivated to combine a touch screen to Lichtenstein for the entering of hemodialysis parameters because Lichtenstein teaches that the operator was never going to be entering parameters into the Lichtenstein machine. In support of this argument, Baxter relies on testimony from its expert, Richard F. Ferraro.[29] *See* Ferraro Decl. at ¶¶ 8, 12-16, 19-20. Mr. Ferraro states that:

> I find no compelling reason, outside of using the patents-in-suit as a blueprint, for adding a touch screen to the medical instrument disclosed in the Lichtenstein '983 Patent. I do, however find there are at least two compelling reasons why not to add a touch screen: (a) there would be no useful function for the touch screen; and (b) Lichtenstein overcomes the problems with the prior art by not relying upon the operator for entering parameters.

Id. at ¶ 15.

The parties are also in dispute as to whether or not the Lichtenstein patent "teaches away" from a user entering operational parameters. "What a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact." *In re Bell*, 991 F.2d 781, 784 (Fed. Cir. 1993). A reference "teaches away" when it suggests that the developments flowing from its disclosures are

[29]Mr. Ferraro has a Master's Degree in Electrical Engineering and has been an electrical engineer for over thirty years. Ferraro Decl. at ¶ 3.

unlikely to produce the objective of the applicant's invention. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Similarly, "a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Tec Air, Inc. v. Denso Mfg. Mich. Inc*, 192 F.3d 1353, 1360 (Fed. Cir. 1999); *see also In re Haruna*, 249 F.3d 1327, 1335-36 (Fed. Cir. 2001). As a "useful general rule," references that teach away cannot serve to create a prima facie case of obviousness. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001).

According to Mr. Ferraro, there is no disclosure in the Lichtenstein patent where an operator inputs hemodialysis parameters through a user interface – as the asserted claims of the '434 and '131 Patents require. Ferraro Decl. at ¶¶ 12-42. To the contrary, Mr. Ferraro contends that Lichtenstein discloses how the microcomputer automatically, under computer program control, operates the machine. *Id.* at ¶¶ 23-27, 39. Mr. Ferraro also asserts that Lichtenstein unmistakably claims to improve on prior art having an "attendant" enter parameters. *Id.* at ¶¶ 24-27; *see also* Abernathy Decl. ISO Opp. to Fresenius MSJ at Ex. 8 (983:1:31-43).[30] Additionally, Baxter points out that, when asked about the teaching of "manual control" in Lichtenstein, Fresenius' own witness, Mr. Causey could only identify one instance where the attendant was instructed by the computer to "shut valves." Abernathy Decl. at Ex. 3 (Causey Depo. at 217-219). Despite his deposition testimony, however, it appears that Mr. Causey disputes Baxter's contention that Lichtenstein teaches away from the claimed invention. Again, this dispute regarding the "teachings" of Lichtenstein makes summary judgment inappropriate.

3. Secondary Considerations

Further, although Fresenius instructs the Court in its Motion that the Court need not evaluate whether any secondary considerations negate a finding of obviousness, such a quick dismissal of one of the *Graham* factors is contrary to law.[31] *See Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851

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[30]While Fresenius attempts to dismiss Mr. Ferraro's testimony as "conclusory," Mr. Ferraro actually cites quite extensively to the Lichtenstein patent in support of each of his opinions.

[31]In fact, Fresenius' only discussion of secondary considerations in its Motion is its instruction for this Court to "look to the [August 2003] Board decision to see why Baxter's arguments regarding secondary considerations must be rejected." As discussed above, this is completely insufficient to carry its burden on summary judgment. This Court may not merely default to the Board's conclusions,

F.2d 1387 (Fed. Cir. 1988) ("The commercial response to an invention is significant to determinations of obviousness, and is entitled to fair weight"). The Federal Circuit has often noted that secondary considerations can be the "most probative and determinative [evidence] of the ultimate conclusion of obviousness or nonobviousness." *See, e.g., Pro Mold v. Great Lakes Plastics*, 75 F.3d 1568, 1572-74 (Fed. Cir. 1996).

Having considered the evidence that Baxter has offered pertaining to the "secondary considerations" factor, it is clear to the Court that this issue, too, is clouded with disputed facts. First, the parties dispute whether the System 1000[32] was commercially successful and, if so, whether the success is sufficiently related to the patented technology.

For example, Baxter argues that the System 1000 enjoyed immediate market acceptance – doubling the highest market penetration of its predecessor – and quickly became state of the art. Turner Decl. ISO Opp. to Fresenius MSJ I at ¶ 5. In support of this assertion, Baxter cites to testimony from its expert, Dr. John Turner, who explains that, between 1992 and 1993, domestic sales of the System 1000 increased by more than 146 percent. *Id.* at ¶ 7. Dr. Turner has also testified that the System 1000 generated more than $19 million in revenue by its second full year of production. *Id.* at ¶ 7. Additionally, Baxter notes that Fresenius' own internal documents reflect the fact that Althin – the owner of the patents-in-suit at the time – continued to maintain a 12 percent market share through 1999. *Id.* at ¶¶ 10-11. Baxter further argues that the marketing and sales materials stressing the benefits of the touch screen operation and the profiling options of the System 1000 show that a nexus existed between the asserted claims of the '434 and '131 Patents and the commercial success of the System 1000.[33] *Id.* at ¶ 12.

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particularly when the Board only considered a total of five documents pertaining to this issue.

[32]There is no dispute that Baxter's System 1000 is covered by the '434 and '131 Patents. In fact, it is incorporated by reference into the Patents.

[33]Baxter also argues that the success of Fresenius' 2008K further shows that there is a nexus between the patented technology and commercial success. *See* Den Uyl Decl. at ¶ 6 (noting that Fresenius' market share increased to sixty-four percent after introduction of Fresenius 2008K); *see also* Turner Decl. at ¶¶ 18-19, 28-35 (opining that Fresenius' sales and marketing materials demonstrate a clear nexus between the patented technology and the success of the 2008K). However, Fresenius' expert, Robert Payne, disputes this conclusion and opines that the patented features did *not* drive sales of the 2008K. *See* March 28, 2006 McClenahan Decl. at Ex. D (Payne Expert Report at ¶ 46).

Fresenius argues, however, that the System 1000 was not successful because Baxter's own data indicates that the peak unit sales of the System 1000 never reached the peak unit sales of the predecessor machine, which did not have the patented touch screen. March 28, 2006 McClenahan Decl. at Exs. B, E.[34] Fresenius further argues that Baxter has not shown that the claimed touch screen features are what drove sales of the System 1000. In fact, Fresenius points out that the relevant marketing and sales literature touted numerous features of the System 1000, not just the touch screen and profiling options. March 28, 2006 McClenahan Decl. at Ex. D (Payne Expert Report at ¶ 35).

The parties also dispute whether Fresenius copied Baxter's patented technology.[35] For example, Fresenius' witness, Mr. Crnkovich,[36] has affirmatively stated that Fresenius did *not* copy the System 1000. Crnkovich Decl. at ¶¶ 7-10. However, Baxter alleges that Fresenius' witnesses admitted using the System 1000 and its manual to develop its own 2008K machine:

> Q. In developing the 2008K, did you have information relating to the Althin System 1000?
>
> A. Yes.
>
> Q. What information did you have?
>
> A. We had an operator's manual.
>
> Q. Did you have anything else?
>
> A. I think we had a machine also.

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[34]Fresenius also argues that Baxter's expert on secondary considerations, Dr. Turner, is "hardly the right person to opine on what drove sales of the System 1000" because he "has never been involved in the design, manufacture, marketing or sale of any hemodialysis machine, let alone the System 1000." Dr. Turner holds a Ph.D. in electrical engineering and computer science from Princeton University and an MBA from the Kellogg School of Management at Northwestern University. Turner Decl. at ¶ 3. He was also a postdoctoral fellow and research associate at Stanford University. *Id.* His medical industry experience includes more than fifteen years of designing, developing, marketing, and manufacturing FDA approved medical devices. *Id.* at ¶ 4. Given Dr. Turner's credentials and experience, Fresenius' criticisms of Dr. Turner are unfounded. Similarly unfounded is Fresenius' argument that Dr. Turner's declaration should be ignored because it is "conclusory." Contrary to Fresenius' assertion, Dr. Turner's declaration is replete with citations to the specific evidence supporting his opinions.

[35]The Federal Circuit has noted that "wholesale copying" provides "compelling evidence of nonobviousness." *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272, 1285-86 (Fed. Cir. 2000).

[36]Mr. Crnkovich is the senior R&D Manager for hemodialysis equipment development at Fresenius. Crnkovich Decl. at ¶ 1.

Ex. 19 (Crnkovich Depo. at 29:4-10. Baxter also asserts that Fresenius' research and development documents confirm that it borrowed heavily from the System 1000. For example, during the early stages of the development process, Fresenius' 2008K Project Manager, Martin Crnkovich, stated: "We are working at developing a touch screen that performs and looks better than the Althin machine." Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 20.

Additionally, Baxter contends that Fresenius' confidential strategic documents reveal that Fresenius intentionally adopted a touch screen user interface in order to protect its market position:

> Our competitors are introducing new machines with a new improved user interface. Each of the machines being introduced has a high-resolution color LCD/CRT display with a touch screen interface. To maintain our competitive edge, we must upgrade the control unit on the 2008H to one that is state of the art.

Id. (emphasis added). Further, Baxter's expert on commercial success, Dr. John Turner, has also opined that Fresenius positioned the 2008K to compete directly against the patented touch screen features of the Althin System 1000. Turner Decl. at ¶¶ 20-21. When this evidence is compared to Mr. Crnkovich's testimony denying that Fresenius copied the System 1000, it is clear that this factual issue is in dispute.

There is also a dispute as to whether there was any skepticism as to the claimed invention's feasibility. Testimony expressing skepticism about an invention's feasibility is an important secondary factor. *The Gillette Company v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725-26 (Fed. Cir. 1990). Baxter contends that testimony from Fresenius' CEO, Dr. Ben Lipps, and R&D Manager, Mr. Crnkovich, support a finding that the marketplace was skeptical about the feasibility of Baxter's patented technology. For example, Dr. Lipps has testified that, in the mid-to-late 1980s, he did not consider touch screens reliable enough to use in the hemodialysis field:

> A. Well, just one of the features of a dialysis machine is it has to be reliable and it has to provide basically the latest therapy, so I tried to get the guys to focus on the sodium variation and the therapy and the reliability. And touch screens at that time were highly unreliable, and they weren't necessary at all as an interface. We sold most of the market using just buttons, okay, because the machine was good, it had great quality. So I kind of brought them back to the reality that it was not economical and not reliable at that point to use a touch screen.

Abernathy Decl. ISO Opp. to Fresenius MSJ at Ex. 24 (Lipps Depo. at 38).

Dr. Lipps also explained that the environment that a hemodialysis machine operated in precluded

the use of a touch screen:

> Q. When you say "reliability wasn't there," describe what you mean.
>
> A. Well, there were two issues. One of them was the length of mean time between failure between - before having a film failure from just operating. And the other one was the environment they operated in where they clean the machines on a regular basis, sometimes between treatments and sometimes once a day, the data did not indicate that these touch screens would hold up at that time, and I was very leery of them.
>
> . . .
>
> Q. And the data you're referring to is data as to use of a touch screen?
>
> A. Whoever manufactures, yeah, they were used in a number of devices and people were - but the use of our device was so heavy in terms of, you know, 20 hours a day, six days a week, that it was just not the right decision at that point from my standpoint.

Id. at Ex. 24 (Lipps Depo. at 65-66).[37]

Fresenius argues, however, that the testimony cited by Baxter does not bear on the issue of technological incompatibility, which is relevant to obviousness, but addresses only whether Fresenius had business concerns, which is not relevant. *See In re Farrenkopf*, 713 F.2d 714, 718 (Fed. Cir. 1983) ("That a given combination would not be made by businessmen for economic reasons does not mean that persons skilled in the art would not make the combination because of some technological incompatibility. Only the latter fact would be relevant.") In support of this assertion, Fresenius cites to testimony from its own witness, Dr. Lipps, who has stated that Fresenius' decision not to implement a touch screen in the 1980s was for business reasons. Lipps Decl. at ¶ 7.

Again, however, Fresenius' argument does not support a finding of summary judgment, it merely supports the conclusion that there are disputed issues of fact that cannot be resolved at summary judgment. *Monarch Knitting Machinery Corp. v. Sulzer Morat Gmbh*, 139 F.3d. 877, 885-86 (Fed. Cir. 1998); *Scripps Clinic*, 927 F.2d at 1578 (noting that "[i]n patent cases, questions by affidavit are disfavored.").

Accordingly, due to the numerous disputed factual issues – including issues that bear directly on Fresenius' prima facie case of obviousness – the Court hereby DENIES Fresenius' Motion for Summary Judgment.

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[37]Mr. Crnkovich echoed this sentiment by stating that he did not "have a good experience" with touch screens in the 1980's. Abernathy Decl. at Ex. 19 (Crnkovich Depo. at 10:8-11:10, 13:20-14:5).

C. Fresenius' "Touch Screen" Best Mode Defense

Next, in its Motion for Partial Summary Judgment of Validity, Baxter has moved for summary judgment on Fresenius' "touch screen" best mode defense. Additionally, Fresenius has separately moved for summary judgment on this issue. Fresenius' "touch screen" best mode defense is premised on its belief that the "touch screen claims" of the patents-in-suit are invalid because they violate the best mode requirement of 35 U.S.C. §112 in that they disclose the use of a "touch screen," but not a "resistive" touch screen.

With respect to this affirmative defense, Fresenius bears the burden of proving, by clear and convincing evidence, that, at the time of filing the patent applications, the inventors of the patents-in-suit considered resistive touch screens to be the best mode for practicing the invention claimed in the patents and nevertheless concealed that fact from the public. *High Street Concrete Structures, Inc.*, 377 F.3d at 1382. Fresenius must also show that the patent specifications are inadequate to enable one of ordinary skill in the art to practice the best mode. *Bayer AG*, 301 F.3d at 1320.[38]

In support of its Motion, Fresenius relies solely on the following evidence: (1) that one of the twelve inventors, Mr. Harley Johnson, preferred resistive touch screens;[39] and (2) that the Elographics part numbers set forth in the patent specification relating to the touch screen and the touch screen controller are wrong. Having reviewed all of the evidence produced by both parties in their cross-motions, the Court concludes that there is no dispute of material fact and that Fresenius has failed to

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[38]With respect to this affirmative defense, Fresenius bears a heavy burden. In fact, in 2002, the Federal Circuit noted that it had held claims invalid for failure to satisfy the best mode requirement on only *seven* prior occasions. *See Bayer AG*, 301 at 1316.

[39]Specifically, Fresenius relies on the following deposition testimony elicited from Mr. Johnson:

> Q: In the SATRN system, . . . did it use a resistive touch screen?
>
> A: Yes.
>
> Q: Why did it use a resistive touch screen?
>
> A: Well, we had experimented with capacitive and [] peizoresistive and the straight resistive screens and found that [] the resistive touch screen was a better performer for [] this product."

Zheng Decl. ISO Opp. to Baxter Mot. to Strike Defenses at Ex. O (Johnson Depo. at 70-71).

meet its burden of proof on this defense.

Neither party disputes that the part numbers disclosed in the patents are inaccurate. However, it is also undisputed that the patents disclose Elographics as the preferred touch screen supplier[40] and that the part numbers do generally relate to Elographics' AccuTouch resistive touch screen product line. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 21 (Phares Depo. at 72:13-75:3). In fact, ninety-five percent of the touch screens sold by Elographics during the relevant period were resistive touch screens. *Id.* (Phares Depo. at 23:19-23). Further, Elographics' product brochures touted the company's "Proven Resistive Technology" for touch screens used in "Medical Instrumentation" and Elographics regularly worked with companies to choose the right screen for their devices. Abernathy Decl. ISO Baxter MSJ at Ex. 20 (Phares Report at ¶ 37); *see also id.* at Ex. 23 (Elographics Product Brochures). In addition to these facts pertaining to Elographics, it is undisputed that resistive touch screens were well known by those skilled in the art at the time the patents issued. In fact, Fresenius' own expert witness, Mr. Causey, admitted to this. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 227).[41] Finally, and significantly, there is absolutely no evidence that any of the inventors intended to conceal the use of resistive touch screens from the public.[42] Again, Fresenius' witness, Mr. Causey, conceded this fact as well. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 234:19-25) ("I'm not aware of an intent to conceal.").

Thus, the undisputed evidence does *not* clearly and convincingly establish that a person of

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[40]For example, the '434 Patent discloses that "Touch screens are known in the art and are commercially available from a number of sources, including Elographics West of San Diego, Calif." *See* 434:8-21, 434:31:38-46.

[41]Q: It was widely known in the field, based on your experience, that resistive touch screens could be used on medical devices, right?

A: Yes. Yes, absolutely.

Q: That's your experience?

A: Yes, my personal experience.

See Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 227:16-21).

[42]In fact, as to eleven of the twelve named inventors, Fresenius has produced no evidence whatsoever.

ordinary skill in the art would be unable to practice the best mode based on the patent specifications. Further, the Federal Circuit has explicitly held that the best mode requirement is "not violated by unintentional omission of information that would be readily known to persons in the field of the invention." *High Concrete, Inc.*, 377 F.3d at 1383. Accordingly, the Court hereby GRANTS summary judgment in Baxter's favor on Fresenius' touch screen claims best mode defense and DENIES Fresenius' Motion for Summary Judgment on this defense.

D. "Extensive Innovation" Enablement and Best Mode Defense

Alternatively, in its Motion for Summary Judgment, Fresenius alleges that the touch screen claims are invalid because they violate *both* the enablement and the best mode requirements of 35 U.S.C. §112 due to the fact that the patents-in-suit do not disclose "extensive innovations."[43] As previously stated, because the grant of a patent by the PTO carries with it the presumption of validity, invalidity for lack of enablement and violation of the best mode requirement must be shown by clear and convincing evidence.

Again, with respect to these affirmative defenses, Fresenius has not met its burden of proof. In fact, Baxter has persuasively shown that it is entitled to summary judgment in its favor because there is an absence of *any* evidence – much less the clear and convincing kind – supporting these affirmative defenses. *Celotex*, 477 U.S. at 325. For example, Fresenius has not set forth any evidence showing that a person of ordinary skill in the art would be unable to practice the claimed inventions based on the actual disclosures in the specifications, including the patents' appendices, which are in excess of 400 pages. Instead, Fresenius' expert, Mr. Phares, has admitted that it would *not* have required undue experimentation to implement a touch screen on any device claimed in the patents-in-suit. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 22 (Phares Report at ¶¶ 51-52).

Indeed, the only "evidence" that Fresenius has cited in its briefing on this issue, which is paltry, relates solely to certain statements made by Baxter's attorneys during patent prosecution and is not

[43]These affirmative defenses also serve as the basis for Baxter's cross-Motion for Partial Summary Judgment of Validity.

relevant to an enablement determination.[44] *Compare with Ajinomoto*, 228 F.3d at 1338 (noting that the district court found the patent enabling after considering extensive expert testimony on the issue). For instance, Fresenius relies on the fact that Baxter argued during prosecution of the family of patents-in-suit that its claims were patentable because providing a hemodialysis machine with a touch screen required extensive innovation in hardware and software. Specifically, Fresenius notes that, during prosecution of the '922 Application, to which the '131 patent claims priority, Baxter argued:

> Providing a hemodialysis machine with a touch screen is not the same as simply adding a different style of gauge to, or changing the arrangement of manual controls on, the front panel of the machine. Rather, providing a hemodialysis machine with a touch screen requires extensive innovation in hardware and software. Lichtenstein and Weiss are completely silent on even how to begin such an endeavor.

McClenahan Decl. ISO Opp. to Baxter MSJ at Ex. Q.

Fresenius also notes that during prosecution of the '434 patent, Baxter stated:

> Contrary to the Examiner's statement in the Office Action, it would not have been obvious to a skilled artisan to substitute, for example, an analog display (as recited in claims 35-37) on a touch screen for a digital display. An analog display requires substantially different software than a digital display. A skilled artisan viewing a digital display as disclosed in Kerns et al. would neither be motivated to devise an analog display nor be provided with any indication of how to provide an analog display on a touch screen by referring to the Kerns et al. disclosure.

Id. at Ex. R.

However, as Baxter points out, these statements were made after all the asserted claims were allowed in relation to an obviousness rejection of claims of a different patent application. Further, according to Baxter, the cited remarks in the '434 Patent prosecution history have nothing to do with providing a touch screen on a hemodialysis device, but rather the motivation to display data in an analog format, rather than a digital format.[45]

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[44]In fact, some of the evidence Fresenius relies on pertains to the prosecution of a separate application, Application No. 09/067,922("'922 Application") which involves claims not at issue here. Arguments made during the prosecution of claims that are not at issue in the instant litigation are not clear and convincing evidence relevant to Fresenius' enablement affirmative defense.

[45]Moreover, although Fresenius claims that Baxter's 30(b)(6) representative, Tom Kelly, a named inventor of the '434 and '131 patents, could not clearly answer Baxter's queries regarding the "innovative" hardware and software, Baxter argues that Mr. Kelly informed Fresenius that the entire host system that controls the dialysis machine and the user interface is innovative. *Id.* at Ex. S (Kelly

Fresenius' argument that the patents fail to disclose the software that controls the machine or the user interface is also unpersuasive. The Federal Circuit has repeatedly held that when the subject matter is a computer program that implements a claimed device, enablement is determined from the viewpoint of a skilled programmer. *See e.g.*, *Northern Telecom*, 908 F.2d at 941. Where software constitutes part of implementing an invention, disclosure of such is satisfied by a description of the functions of the software. *Fonar Corp. v. General Elect. Co.*, 107 F.3d 1543, 1549 (Fed. Cir. 1997). Flow charts or source code listings are not a requirement for adequately disclosing the functions of software. *Fonar Corp.*, 107 F.3d at 1549; *Robotic Vision Sys., Inc. v. View Engineering, Inc.*, 112 F.3d 1163, 1166 (Fed. Cir. 1997) (finding sufficient disclosure because the functions required for software to instruct the computer to control the machine are apparent from the specification to one of ordinary skill in the art).

Here, Baxter has cited to evidence showing that the specification provides ample details and functionality of the system required to provide a touch screen user interface for displaying and changing operational parameters of a hemodialysis machine. For example, the '434 Patent specification discloses that "[t]erminate and stay resident software for driving the interface board . . . is available from Elographics," which is the software that controls the touch screen controller and provides information to the system that the touch screen has been touched. 434:13:44-46. It also describes the host control program, which provides for, *inter alia*: data input from the touch screen, data gathering from various controller sub-systems (including the blood pump, I/O, and ultrafiltration), outputting control functions to the various sub-systems, monitoring and evaluating the data, and displaying the data to the touch screen user interface. 434:13:1-17. Software flow diagrams for various software modules used to control the hemodialysis machine are also provided. *See, e.g.*, 476:237-262.

As for the software application for the user interface, the patent specification contains numerous descriptions and examples of screen layout, design, and application functionality for setting, modifying, and displaying various hemodialysis treatment parameters, including time-variable treatment parameters. *See, e.g.*, 434:8:42-11:39. Fresenius has produced no evidence that a skilled programmer, using these disclosures as a blueprint, would be unable to practice the inventions. As such, the Court GRANTS

Depo. at 92:6-7, 97:11-24).

Baxter's Motion for Summary Judgment on Fresenius' enablement and best mode defenses.

CONCLUSION

IT IS HEREBY ORDERED THAT Baxter's Motion for Partial Summary Judgment of Validity [Docket No. 448] is GRANTED. Baxter is entitled to summary judgment in its favor on Fresenius' affirmative defenses of enablement and best mode, as well as judgment in its favor that the Sarns 9000 does not anticipate the asserted claims of the '131 and '434 Patent.

IT IS FURTHER ORDERED THAT Fresenius' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131 [Docket No. 436] is DENIED. Fresenius' 35 U.S.C. § 103 obviousness affirmative defense shall be resolved by the trier of fact.

IT IS SO ORDERED.

Dated: 5/16/06

SAUNDRA BROWN ARMSTRONG
United States District Judge